United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued March 13, 1998 Decided April 14, 1998

No. 97-5082

Mova Pharmaceutical Corp.,

Appellee

v.

Donna E. Shalala,

Secretary, U.S. Department of Health & Human Services and

Michael A. Friedman, Acting Commissioner, U.S. Food and Drug Administration, Appellees

Mylan Pharmaceuticals, Inc.,

Appellant

Consolidated with

No. 97-5111

Appeals from the United States District Court

for the District of Columbia

(No. 96cv02861)

Steven Lieberman argued the cause for appellant Mylan Pharmaceuticals, Inc., with whom E. Anthony Figg was on the briefs.

Howard S. Scher, Attorney, United States Department of Justice, argued the cause for the federal appellants, with whom Frank W. Hunger, Assistant Attorney General, Mary Lou Leary, United States Attorney at the time the briefs were filed, and Douglas N. Letter, Litigation Counsel, were on the briefs.

Steven J. Glassman argued the cause for appellant Pharmacia & Upjohn Company, with whom David O. Bickart was on the briefs.

Ronald L. Grudziecki argued the cause for appellee, with whom James S. Rubin was on the brief.

John F. Cooney filed the brief for amicus curiae Teva Pharmaceuticals, USA.

Before: Wald, Silberman and Tatel, Circuit Judges.

Opinion for the Court filed by Circuit Judge Wald.

Wald, Circuit Judge: On December 19, 1996, the Food and Drug Administration ("FDA") approved an application by a drug manufacturer, Mylan Pharmaceuticals, Inc. ("Mylan") to market a generic version of micronized glyburide, a drug used to treat diabetes. Another drug manufacturer, Mova Pharmaceutical Corp. ("Mova"), had filed an earlier application to market a generic version of the same drug; however, Mova's application had not yet been approved, because of a patent infringement suit brought by Pharmacia & Upjohn Company ("Upjohn"), in which Upjohn claimed that Mova's product infringed a patent belonging to Upjohn.

When Mova learned that the FDA had approved Mylan's application, it brought suit in the United States District Court for the District of Columbia, relying on 21 U.S.C. s 355(j)(5)(B)(iv) (1994),1 to compel the FDA to delay the

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1 At the time that Mova brought its action, this section was designated 21 U.S.C. s 355(j)(4)(B)(iv). On November 21, 1997, the

effective date of this approval until 180 days after the earlier of the dates that Mova won its suit or began to market its product. Because the statutory scheme governing the approval of successive generic drug applications is quite complex, we will, for purposes of the introduction, describe the parties' contentions only in general terms. Mova argued that, because it had filed a previous application to market a generic version of micronized glyburide, the applicable statutory provision, 21 U.S.C. s 355(j)(5)(B)(iv), granted a 180-day market exclusivity period to Mova running from the date Mova won its suit or began marketing its product, and the FDA was barred from approving Mylan's similar application until after the end of that 180-day period. In response, the FDA cited a regulation that permitted the agency to approve Mylan's application immediately, because at the time Mylan submitted its application Mova had not yet "successfully defended" against (that is, prevailed in) Upjohn's patent infringement suit. See 21 C.F.R. s 314.107(c)(1). Mova in turn challenged the FDA's regulation as inconsistent with the plain language of s 355(j)(5)(B)(iv). The district court agreed with Mova, and entered a preliminary injunction requiring the FDA to delay its approval of Mylan's application until 180 days after Mova won its suit or began to market its product (whichever came first). The FDA and Mylan have appealed this decision.

While Mova's request for a preliminary injunction was pending, Upjohn submitted a motion to intervene in the litigation. After granting the injunction, the district court denied Upjohn's motion to intervene, concluding that it was moot, and that in any case Upjohn did not have a legally protected interest in the subject matter of the litigation.

Food and Drug Administration Modernization Act of 1997 was enacted; section 119(b)(1)(A) of that law inserted a new section 355(j)(3), and redesignated former paragraphs 355(j)(3) to (8) as paragraphs (4) to (9). See Pub. L. No. 105-115, 111 Stat. 2296 (1997). According to section 501 of that Act, the amendments "shall take effect 90 days after the date of enactment of this Act." We will therefore use the section's new designation.

Upjohn has appealed this ruling and its appeal has been consolidated with that of the FDA and Mylan.

On the merits of the preliminary injunction, we find that the district court was correct in finding that Mova was very likely to be able to show that the FDA's regulation exceeded its authority under the statute. On Upjohn's motion to intervene, we find that the district court's reasons for denying the motion were erroneous, and that Upjohn is entitled to participate both in this appeal and in any further proceedings before the district court.

I. Background

A.Statutory and Regulatory Framework

We will first briefly outline the statutory and regulatory framework applicable to the marketing of generic drugs. Generic drugs are versions of brand-name prescription drugs that are often sold without a brand name and that contain the same active ingredients, but not necessarily the same inactive ingredients, as the original. United States v. Generix Drug Corp., 460 U.S. 453, 455 (1983). Ordinarily, an applicant to market a drug must complete a document called a New Drug Application, or NDA. Preparing such applications can be a time-consuming and costly process, as they must include data from studies showing the drug's safety and effectiveness. Formerly, a firm that wished to make a generic version of a brand-name drug that had already been approved by the FDA was required to file a new NDA, complete with new studies showing the drug's safety and effectiveness. See generally H.R. Rep. No. 98-857, Part I, at 16-17 (1984).

In 1984, Congress enacted the Hatch-Waxman Amendments, which established a simplified procedure for FDA approval of generic drugs. Under this procedure, the original applicant for FDA approval of a drug, called the "pioneer" applicant, must still complete a full NDA. However, subsequent applicants who wish to manufacture generic versions of the original have an alternative: they may instead complete an Abbreviated New Drug Application, or ANDA, which relies on the FDA's previous determination that the drug is

safe and effective, and thus avoid submitting new safety and effectiveness studies.

The Hatch-Waxman Amendments specify the contents of an ANDA in detail. One requirement is that, for each of the patents applicable to the pioneer drug, the ANDA applicant must certify whether the proposed generic drug would infringe that patent, and, if not, why not. The statute provides ANDA applicants with four certification options: they may certify (I) that the required patent information has not been filed; (II) that the patent has expired; (III) that the patent has not expired, but will expire on a particular date; or (IV) that the patent is invalid or will not be infringed by the drug for which the ANDA applicant seeks approval. 21 U.S.C. s 355(j)(2)(A)(vii). We will call these paragraph I, II, III, and IV certifications, respectively.

If the applicant makes a certification under paragraphs I or II, the statute provides that the FDA may approve the ANDA effective immediately. 21 U.S.C. s 355(j)(5)(B)(i). If the applicant makes a certification under paragraph III, the FDA may approve the ANDA effective on the date that the applicant certifies that the patent will expire. 21 U.S.C. s 355(j)(5)(B)(ii).

When an applicant makes a certification under paragraph IV, things become more complicated. In such cases, the statute begins by providing a forty-five-day window during which the patent-holder may bring suit against the applicant. If the patent-holder brings suit during that forty-five-day period, the statute says that the FDA's approval of the ANDA must be delayed for thirty months, a provision that is presumably intended to allow the patent-holder time to vindicate its patent in court before the generic competitor is allowed entry into the market. 21 U.S.C. s 355(j)(5)(B)(iii). The statute permits the court to lengthen or shorten this period if it finds that either party has failed to "reasonably cooperate in expediting the action." Id. If the court finds that the patent is invalid or is not infringed, the FDA's approval becomes effective as of the date of that ruling. 21

U.S.C. s 355(j)(5)(B)(iii)(I), (III).2

It is the succeeding provision of the statute, however, that has occasioned the dispute involved in this suit (and many others). That provision says:

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2 The full text of section 355(j)(5)(B)(iii) reads:

> If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that--
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> (I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,
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> (II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of Title 35 or
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> (III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.
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> In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of Title 28 for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

> If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing [sic] 3 such a certification, the application shall be made effective not earlier than one hundred and eighty days after--
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> (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
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> (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

21 U.S.C. s 355(j)(5)(B)(iv). This provision on its face appears to provide an advantage to the first party who files a paragraph IV ANDA (henceforth, the "first applicant"), by granting him a 180-day period in which to market his generic drug without competition from other ANDA applicants.4 We will call this Edenic moment of freedom from the pressures of the marketplace the statute's "exclusivity period." Section 355(j)(5)(B)(iv) has two sub-clauses, each of which can trigger the start of the 180-day exclusivity period; we will call sub-clause (I), which turns on the first commercial marketing of the drug, the "commercial-marketing trigger," and sub-clause (II), which turns on a court decision finding the patent to be invalid or not infringed, the "court-decision trigger."

The FDA, however, concluded, for reasons discussed below, that Congress could not have intended for this provision to be read literally. Thus, in drafting the regulations implementing

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3 This should probably read "containing."

4 The statute actually says that the exclusivity period applies whenever there is a "previous" application; thus, the statute might conceivably be read to confer this 180-day period on a second or third applicant in some situations. For purposes of this litigation, however, the only previous application is Mova's, which is also the first. We will therefore refer only to the first applicant.

section 355(j)(5)(B)(iv), the FDA added its own requirement that the first applicant must have "successfully defended against a suit for patent infringement" before the exclusivity period can begin to run. (We will refer to this as the "successful defense" requirement.) The relevant regulation states:

> If an abbreviated new drug application contains a certification that a relevant patent is invalid, unenforceable, or will not be infringed and the application is for a generic copy of the same listed drug for which one or more substantially complete abbreviated new drug applications were previously submitted containing a certification that the same patent was invalid, unenforceable, or would not be infringed and the applicant submitting the first application has successfully defended against a suit for patent infringement brought within 45 days of the patent owner's receipt of notice submitted under s 314.95, approval of the subsequent abbreviated new drug application will be made effective no sooner than 180 days from whichever of the following dates is earlier:
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> > (i) The date the applicant submitting the first application first commences commercial marketing of its drug product; or
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> > (ii) The date of a decision of the court holding the relevant patent invalid, unenforceable, or not infringed.

21 C.F.R. s 314.107(c)(1) (emphasis added).

B.The Factual Scenario of This Case

Glyburide is a drug used in treating diabetes, and micronized glyburide is one form of that drug. Upjohn holds a patent for a particular formulation of micronized glyburide entitled "Spray-Dried Lactose Formulation of Micronized Glyburide."

In December, 1994, Mova filed an ANDA for a generic form of micronized glyburide, which included a paragraph IV certification. Mova gave the required notice to the patentholder, Upjohn; within 45 days of receiving this notice,

Upjohn filed a patent infringement suit against Mova in the District of Puerto Rico.

While this litigation was underway, in November, 1995, Mylan, too, filed an ANDA for a generic form of micronized glyburide. Mylan's initial filing contained a paragraph III certification; this meant that Mylan conceded patent infringement, so that its ANDA could not receive FDA approval until Upjohn's patent expired. In August 1996, however, Mylan amended its ANDA to contain a paragraph IV certification.

As Mova had, Mylan gave the required notice to Upjohn; but this time Upjohn, for reasons unclear, failed to sue within the prescribed 45-day period.5 The thirty-month suspension of FDA approval provided for in section 355(j)(5)(B)(iii) only applies if the patent-holder sues the ANDA applicant within 45 days; thus, this waiting period did not apply to Mylan. And, because Mova had not yet "successfully defended" against Upjohn's patent infringement suit, 21 C.F.R. s 314.107(c)(1), which incorporates the FDA's interpretation of section 355(j)(5)(B)(iv), did not require the FDA to delay its approval of Mylan's ANDA. Thus, the FDA approved Mylan's ANDA effective immediately, as of December 19, 1996.

After learning of this approval, Mova, on December 26, 1996, filed suit in the United States District Court for the District of Columbia, seeking a temporary restraining order compelling the FDA to postpone the effective date of Mylan's approval. Although declining to issue a TRO, the district court, on January 23, 1997, granted a preliminary injunction requiring that the FDA render its approval of Mylan's ANDA effective no earlier than 180 days after the earlier of (1) Mova's first commercial marketing of its micronized glyburide product, or (2) the date of Mova's victory in the Puerto Rico litigation. (This was precisely the relief Mova had sought.) In an accompanying memorandum, the district court explained that the successful-defense requirement in the FDA's regulations was inconsistent with the plain language of section 355(j)(5)(B)(iv), and therefore unenforceable. The FDA

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5 Upjohn did eventually sue Mylan, on February 17, 1997. On March 31, 1998, the court ruled that Upjohn's patent was invalid and not infringed.

and Mylan (which had intervened in the proceedings) appealed.

One further matter remained to be resolved. Before the preliminary injunction was issued, Upjohn had filed a motion seeking to intervene in the proceedings before the district court. The district court had not adverted to this motion in granting the preliminary injunction. A few days later, however, on February 10, it denied Upjohn's motion to intervene, stating that the motion was moot (because the district court had already issued the preliminary injunction), and also that Upjohn did not have a "cognizable interest" in the litigation, and was therefore not entitled to intervene. Upjohn has appealed this order, and argues that it should be allowed to participate in this appeal and in any further proceedings in the district court.

While these appeals were pending, there have been subsequent developments in Upjohn's patent infringement suit against Mova. On December 2, 1997, a jury found that Upjohn's patent was invalid, unenforceable, and had not been infringed. Mova received final approval from the FDA to market its product on December 22, and began to sell its product shortly afterwards. By its terms, the district court's preliminary injunction will therefore expire 180 days after December 2, 1997, on May 31, 1998.

II. Analysis

A.The Preliminary Injunction

To demonstrate entitlement to a preliminary injunction, a litigant must show "1) a substantial likelihood of success on the merits, 2) that it would suffer irreparable injury if the injunction is not granted, 3) that an injunction would not substantially injure other interested parties, and 4) that the public interest would be furthered by the injunction." Cityfed Financial Corp. v. Office of Thrift Supervision, 58 F.3d 738, 746 (D.C. Cir. 1995). The district court balances the litigant's showings in these four areas in deciding whether to grant an injunction. Id. at 747. "We review a district court's decision regarding a preliminary injunction for abuse of dis-

cretion, and any underlying legal conclusions de novo." Id. at 746.

Balancing these factors, the district court found, as to the first, that Mova had a "very high" likelihood of success on the merits, because Mova would probably be able to show that the FDA's successful-defense requirement was contrary to the plain language of section 355(j)(5)(B)(iv) and therefore unenforceable. As to the second, the district court found that "the earliest generic drug manufacturer in a specific market has a distinct advantage over later entrants," and that Mova, a small company, would find it extremely difficult to compete against the much larger Mylan if Mylan got its product to market first. As to the third prong, the district court found that any harm to Mylan was small, because Mylan was so likely to lose on the merits. And, as to the fourth, the district court found that the public was the principal other interested party, and that the public's interest in the "faithful application of the laws" outweighed its interest in immediate access to Mylan's generic product.

The FDA and Mylan have not seriously contested the district court's findings as to the second, third and fourth factors.6 However, they both vigorously contest the district court's conclusion that the successful-defense requirement is

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6 The FDA notes that "the mere existence of competition is not irreparable harm, in the absence of substantiation of severe economic impact." WMATA v. Holiday Tours, 559 F.2d 841, 843 n.3 (D.C. Cir. 1977). Here, however, the district court found that Mova would be harmed by the loss of its "officially sanctioned head start," and that Mova's small size put it at a particular disadvantage. This suffices to show a severe economic impact to Mova.

Both the FDA and Mylan also contend that the district court should have declined to issue a preliminary injunction in order to further the public's interest in the rapid movement of generic drugs into the marketplace. Supposing that they are right in their assessment of the public's interest, however, this factor alone cannot support denying an injunction. Our polity would be very different indeed if the courts could decline to enforce clear laws merely because they thought them contrary to the public interest; we decline to embark upon that path.

inconsistent with section 355(j)(5)(B)(iv). We will focus on the FDA's arguments, because it is on an agency's own justifications that the validity of its regulations must stand or fall. See SEC v. Chenery Corp., 318 U.S. 80 (1943).

The FDA concedes that the text of section 355(j)(5)(B)(iv) makes no provision for a successful-defense requirement. It asserts, however, that a literal reading of that statutory provision would produce consequences of a kind Congress could not have intended when it wrote the law, and that its interpolation of a successful-defense requirement is an appropriate way of implementing Congress's underlying intent.

The FDA points to two principal situations in which a literal reading of the statute would produce bizarre results: (1) cases in which the first applicant is never sued, and (2) cases in which the first applicant loses its suit. If the first applicant is never sued, the FDA claims, then the court-decision trigger will never be satisfied. Later ANDA applicants will be unable to market their products until the first applicant decides to put its product on the market, thereby satisfying the commercial-marketing trigger. But the first applicant could in theory wait indefinitely to begin selling its product, and thereby block all sales by later applicants. This unfortunate scenario could happen, for instance, if the first applicant colludes with the pioneer drug company to eliminate generic competition, or if the first applicant is simply unable to obtain FDA approval of its production facilities and so cannot put its product on the market.

If the first applicant loses its infringement suit, the delay problem could be even more serious. The first applicant would then be able to satisfy neither the court-decision trigger nor the commercial-marketing trigger (because, having lost a patent-infringement suit, it would be unable to sell its product). Thus, the FDA claims, no generic drugs could enter the market until after the pioneer company's patent expired.

The successful-defense requirement, according to the FDA, is calculated to eliminate both occurrences. An applicant that is never sued or that loses its suit will not have "successfully

defended against a suit for patent infringement," 21 C.F.R. s 314.107(c)(1), and so the exclusivity period will not apply. Such applicants will therefore not interfere with the orderly movement by successive applicants of generic drugs into the marketplace.

1. Applicable Principles of Judicial Review

In assessing the validity of an agency's interpretation of a statute, we begin by asking whether "Congress has directly spoken to the precise question at issue"; if so, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43 (1984). If we find that "the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." Id. at 843.

In the district court's judgment, the FDA's pragmatic reading of the statute could not survive the first prong of Chevron. Concluding that the language of the statute "may be complex, and even cumbersome, but it is plain and unambiguous," and that the statute "does not include a 'successful defense' requirement, and indeed it does not even require the institution of patent litigation," the district court found that, under the plain language of the statute, if a paragraph IV ANDA has been filed by a prior applicant, the FDA must delay approval of all subsequent ANDAs until either the court-decision trigger or the commercial-marketing trigger is satisfied.

We think that the district court achieved the right result, but we are not quite as sanguine as the district court that, in applying the first prong of Chevron, it suffices to look only at the plain language of the statute. "[I]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." Pilot Life Insurance Co. v. Dedeaux, 481 U.S. 41, 51 (1987); see also McCarthy v. Bronson, 500 U.S. 136, 139 (1991). Here, the FDA cannot point to any particular ambiguity in the words of section 355(j)(5)(B)(iv)

that permits it to interpolate its "successful defense" requirement. Instead, the FDA's argument is that a literal reading of the statute would thwart Congress's central goal, in enacting the Hatch-Waxman Amendments, to bring generic drugs onto the market as rapidly as possible.

In effect, the FDA seeks to invoke the long-standing rule that a statute should not be construed to produce an absurd result. "It is a familiar rule, that a thing may be within the letter of the statute and yet not within the statute, because not within its spirit nor within the intention of its makers.... If a literal construction of the words of a statute be absurd, the act must be so construed as to avoid the absurdity." Holy Trinity Church v. United States, 143 U.S. 457, 459-60 (1892); see also United States v. X-Citement Video, Inc., 513 U.S. 64, 68-69 (1994) (rejecting the "most natural grammatical reading" of a statute to avoid "absurd" results); Green v. Bock Laundry Machine Company, 490 U.S. 504, 527, 527-29 (1989) (Scalia, J., concurring); In re Nofziger, 925 F.2d 428, 434 (D.C. Cir. 1991); Veronica M. Dougherty, Absurdity and the Limits of Literalism, 44 Am. U.L. Rev. 127 (1994). Over a hundred years ago, the Court explained this rule thus:

> The common sense of man approves the judgment mentioned by Puffendorf, that the Bolognian law which enacted "that whoever drew blood on the streets should be punished with the utmost severity," did not extend to the surgeon who opened the vein of a person who fell down on the street in a fit. The same common sense accepts the ruling, cited by Plowden, that the statute of 1st Edward II, which enacts that a prisoner who breaks prison shall be guilty of a felony, does not extend to a prisoner who breaks out when the prison is on fire--"for he is not to be hanged because he would not stay to be burnt."

United States v. Kirby, 74 U.S. (7 Wall.) 482, 487 (1868) (citations omitted).

In deciding whether a result is absurd, we consider not only whether that result is contrary to common sense, but also whether it is inconsistent with the clear intentions of the

statute's drafters--that is, whether the result is absurd when considered in the particular statutory context. If " 'the literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters,' ... the intention of the drafters, rather than the strict language, controls." United States v. Ron Pair Enterprises, 489 U.S. 235, 242 (1989) (quoting Griffin v. Oceanic Contractors, Inc., 458 U.S. 564, 571 (1982)); see also Environmental Defense Fund, Inc. v. EPA, 82 F.3d 451, 468 (D.C. Cir. 1996) (applying Ron Pair).

The rule that statutes are to be read to avoid absurd results allows an agency to establish that seemingly clear statutory language does not reflect the "unambiguously expressed intent of Congress," Chevron, 467 U.S. at 842, and thus to overcome the first step of the Chevron analysis. But the agency does not thereby obtain a license to rewrite the statute. When the agency concludes that a literal reading of a statute would thwart the purposes of Congress, it may deviate no further from the statute than is needed to protect congressional intent. Of course, the agency might be able to show that there are multiple ways of avoiding a statutory anomaly, all equally consistent with the intentions of the statute's drafters (and equally inconsistent with the statute's text). In such a case, we would move to the second stage of the Chevron analysis, and ask whether the agency's choice between these options was "based on a permissible construction of the statute." Id. at 843. Otherwise, however, our review of the agency's deviation from the statutory text will occur under the first step of the Chevron analysis, in which we do not defer to the agency's interpretation of the statute.

Here, we think that the FDA's interpretation cannot survive analysis under the first step of Chevron. The FDA's "successful defense" requirement achieves the FDA's stated goal of preventing first applicants who are not sued or who lose their suits from benefiting from the exclusivity period. But it also does more. The FDA had two routes by which it could have addressed the problem of first applicants who lose their suits, which we will call the "wait-and-see" approach and the "win-first" approach. Under the wait-and-see option, later applicants would need to wait to see whether the first

applicant won or lost its patent infringement suit. If the first applicant lost, the exclusivity period would not apply; if he won, it would.7 The FDA chose the other option, the win-first approach. Under this approach, later applicants do not need to wait to see whether the first applicant wins or loses. Instead, while the first applicant's litigation is underway, the FDA may approve the applications of later ANDA applicants effective immediately, if they are otherwise eligible for approval.8 Thus, the first applicant must win its lawsuit before section 355(j)(5)(B)(iv) has any effect on subsequent applicants at all.

It is the FDA's decision to adopt the win-first approach that led to the present litigation. If the FDA had instead chosen the wait-and-see approach, the FDA could not have approved Mylan's application when it did; instead, Mylan would have needed to wait for the end of Mova's patent infringement suit. We will therefore focus on this aspect of the successful-defense requirement.

We conclude that the FDA's successful-defense requirement is inconsistent with the unambiguously expressed intent of Congress. The rule is gravely inconsistent with the text and structure of the statute. Nor can the FDA show that the successful-defense requirement is needed to avoid "a result demonstrably at odds with the intentions of [section 355(j)(5)(B)(iv)'s] drafters." Ron Pair Enterprises, 489 U.S. at 242. The FDA could have adopted a more narrow solution to the problem of first applicants who are never sued or who lose their suits. It instead adopted the broad win-first rule, which it cannot show is needed to implement congressional intent. In effect, the FDA has embarked upon an adventurous transplant operation in response to blemishes in the

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7 We do not mean to foreclose a third possibility, which is that some lawsuit other than that against the first applicant might satisfy the court-decision trigger before the first applicant's suit is over. We discuss this possibility below.

8 That is, if they have not been sued by the patent-holder, and are therefore not subject to the 30-month waiting period, or if the 30-month period has expired.

statute that could have been alleviated with more modest corrective surgery.

2. The Statute's Text and Structure

Section 355(j)(5)(B)(iv) is far from a model of legislative draftsmanship. The district court in this case called the provision "cumbersome"; another district court described it as "very confusing and ambiguous." Mylan Pharmaceuticals, Inc. v. Sullivan, No. 89-36-C(K), slip op. at 6 (N.D.W.V. May 5, 1989). But, to the extent that the statute is clear about anything, it clearly forecloses the FDA's successful-defense requirement.9

The successful-defense requirement is inconsistent with the literal language of the statute. Section 355(j)(5)(B)(iv) says that, if an applicant has already filed a paragraph IV ANDA, later applications shall be approved "not earlier than one hundred and eighty days after" the commercial-marketing trigger or the court-decision trigger is satisfied. The FDA's successful-defense requirement, by contrast, permits later applications to be approved even though neither trigger has been satisfied, simply because the first applicant's litigation has not yet come to a successful conclusion.

The win-first rule also infringes on the statutory scheme in a second, subtler way: its practical effect is to write the commercial-marketing trigger out of the statute. The commercial-marketing trigger seems intended to ensure that, if a first ANDA applicant chooses to begin marketing its product before it has won its patent-infringement suit, the 180-day exclusivity period will begin to run immediately. Under the FDA's regulation, however, the 180-day exclusivity period is only available to an applicant who has already "successfully defended against a suit for patent infringement." Thus, if the first applicant begins marketing its product before it wins its

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9 We note that the Fourth Circuit recently came to the same conclusion in an unpublished opinion. See Granutec, Inc. v. Shalala, Nos. 97-1873, 97-1874, slip op. at 13-14 (4th Cir. Apr. 3, 1998). Because the rules of the Fourth Circuit disfavor (but do not prohibit) citation of unpublished opinions, we will not discuss the reasoning of Granutec further.

infringement suit, the 180 days of exclusivity do not begin to run; other applicants remain eligible for FDA approval to begin marketing their products, at least up to the date that the first applicant wins the infringement action.

If the first applicant eventually wins its lawsuit, the exclusivity period is counted as though it had begun to run when the applicant started commercial marketing. Thus, an applicant who begins commercial marketing 120 days before winning its lawsuit receives only 60 days of exclusivity; an applicant who begins commercial marketing 180 days (or more) before winning its suit receives no exclusivity period at all. The FDA thus construes the commercial-marketing trigger to potentially hurt, but never benefit, the first ANDA applicant.

There is no indication in the text or history of section 355(j)(5)(B)(iv) that the commercial-marketing trigger is supposed to function in that one-sided manner. The FDA itself provided a more plausible explanation of how it should work in an initial notice of proposed rulemaking for the ANDA regulations. As the FDA then explained the statutory scheme,

> Congress's decision to begin the 180-day period under section 505(j)(4)(B)(iv)(I) of the act from "the first commercial marketing of the drug," rather than from the effective date of the ANDA, serves a rational policy only if Congress contemplated a situation in which an approval of an ANDA is in effect but the applicant's decision not to market the drug deserves to be protected because a delay in marketing serves the public interest.
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> Such a situation occurs where, under the terms of section 505(j)(4)(B)(iii) of the act, an ANDA goes into effect 30 months after a lawsuit is filed, but the lawsuit is still pending. It serves the public interest to permit a prudent ANDA holder in that situation to stay off the market until the litigation is resolved, thereby minimizing potential damages.
>
> As drafted, sections 505(j)(4)(B)(iv)(I) and (II) of the act carefully avoid providing an incentive for immediate marketing; the 180-day reward of exclusive marketing begins when the applicant wins the lawsuit or when the

> applicant actually begins marketing, "whichever is earlier." The applicant thus does not lose any of the 180-day period by electing to stay off the market until the lawsuit is over.

Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,894 (1989). In other words, the 180-day exclusivity period should begin to run as soon as the first applicant begins commercial marketing. In adopting the successful-defense requirement in its final rulemaking, the FDA neither rejected the foregoing analysis, nor explained how the successful-defense requirement would be consistent with it. See Abbreviated New Drug Application Regulations, 59 Fed. Reg. 50,338, 50,353 (1994).10

3. Does a Literal Reading Produce Absurd Results?

The FDA contends that the statute should not be read literally, because such a reading would produce results that are clearly inconsistent with the intent of Congress in enacting the statute. We do not think that it is sufficiently clear that Congress intended the "win-first" reading of the statute to justify disregarding the most natural reading of the statutory text.

We begin by setting aside the problems of the first applicant who is never sued or who loses his lawsuit. The FDA may or may not be right that a literal reading of the statute to permit a first applicant to receive an exclusivity period in these situations would be inconsistent with the statutory scheme; we do not decide this question. As we have already pointed out, the fatal flaw in the FDA's "absurd results" argument is that the agency could have addressed these two (supposedly) problematic situations without imposing the broad win-first rule by creating narrower exceptions to sec-

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10 The FDA said only that "[o]ne comment said the rule, as drafted, created an incentive for frivolous claims of patent invalidity or noninfringement because it would give ANDA applicants exclusivity even if the applicant was unsuccessful in defending against the patent owner's lawsuit. The comment would replace the phrase 'to be sued within 45 days' with 'and to successfully defend a suit brought within 45 days.' The FDA agrees and has amended s 314.107(c) accordingly." Abbreviated New Drug Application Regulations, 59 Fed. Reg. 50,338, 50,353 (1994).

tion 355(j)(5)(B)(iv) for the "no suit" and "lost suit" cases. Indeed, the FDA has come close to doing so already. As for first applicants who are never sued, the initial draft of 21 C.F.R. s 314.107(c)(1) contained, instead of the successful-defense requirement, only a requirement that the first applicant have been "sued for patent infringement within 45 days of the patent owner's receipt of notice" in order to be eligible for the statutory period. Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,929 (1989). This language would have corrected the problem of first applicants who are never sued (and only that problem).11

As to first applicants who lose their suits, Mova observed at oral argument that one of the FDA's current regulations suggests a possible way of addressing this problem (and indeed may already have solved it). That regulation provides that, if an ANDA applicant who makes a certification under paragraph IV later loses its patent-infringement suit, it must amend its ANDA to make a new certification under paragraph III, and provides that the ANDA will then "no longer be considered to be one containing a certification under paragraph [IV]." 12 The FDA claims that the regulation does

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11 Even this may not be the narrowest way of resolving the underlying problem. After all, Congress may have intended to reward the first ANDA applicant for his enterprise whether or not he is later sued; the statutory scheme only runs into problems if the first applicant never starts selling his product. An alternative might be to prescribe a period within which a first applicant who has not been sued must bring his product to market in order to benefit from the exclusivity period.

12 The relevant regulation provides:

> An applicant who has submitted a certification under paragraph (a)(12)(i)(A)(4) of this section and is sued for patent infringement within 45 days of the receipt of notice sent under s 314.95 shall amend the certification if a final judgment in the action against the applicant is entered finding the patent to be infringed. In the amended certification, the applicant shall certify under paragraph (a)(12)(i)(A)(3) of this section that the patent will expire on a specific date. Once an amendment or letter for the change has been submitted, the application will no

not have the effect of rendering the exclusivity period inapplicable after such an amendment, and of course we owe deference to the agency on the interpretation of its own regulations.13 But even if the present version of the regulation does not accomplish the desired end, the FDA could presumably draft a regulation that did so.

The FDA did not choose to adopt these narrower approaches; instead, it adopted the "win-first" reading of the statute, which deviated from the literal language of the statute by allowing an application to be approved while the first applicant's lawsuit was pending and before either statutory trigger had been satisfied. In analyzing the successful-defense requirement, then, we must ask whether the win-first reading is needed to avoid "a result demonstrably at odds with the intentions of [section 355(j)(5)(B)(iv)'s] drafters." Ron Pair Enterprises, 489 U.S. at 242.

The FDA did not explain its decision to adopt the win-first approach (instead of a narrower approach) in issuing its regulation, see 59 Fed. Reg. 50,338, 50,353 (1994), and it has not presented any argument for that approach in this litigation. There is, however, a compelling argument for the win-first approach, which is advanced by Mylan. What if the first

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> longer be considered to be one containing a certification under paragraph (a)(12)(i)(A)(4) of this section. If a final judgment finds the patent to be invalid and infringed, an amended certification is not required.

21 C.F.R. s 314.94(a)(12)(viii)(A).

13 The FDA said at oral argument that its regulation is intended only for "housekeeping" purposes, and that it should not be read to affect the application of section 355(j)(5)(B)(iv). We owe "substantial deference" to an interpretation by the FDA of its own regulations, which has "controlling weight unless it is plainly erroneous or inconsistent with the regulation." S.G. Loewendick & Sons, Inc. v. Reich, 70 F.3d 1291, 1294 (D.C. Cir. 1995) (quoting Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994)). We confess to not understanding how the FDA can reconcile its reading with the language of its own regulation, but stress that this issue has not been briefed and is not necessary to the decision in this case.

applicant does a poor job of designing its product to avoid infringing the patent-holder's patent, and the second applicant does a much better job? The first applicant would then be sued for infringement by the patent-holder, but the second applicant would not. Indeed, this is exactly what Mylan claims happened in the present case (although Mova vigorously contests this claim).

In such a situation, a literal reading of the statute admittedly produces a strange result. The second applicant, even though it has designed its product well and avoided suit, is barred from selling its product until the first applicant's lawsuit finishes (maybe years later). The ingenious second applicant is thus harmed, and the public is deprived of the fruits of its ingenuity--a result seemingly at odds with Congress's apparent purposes, in enacting section 355(j)(5)(B)(iv), of rewarding innovation and bringing generic drugs to market quickly. Indeed, the first applicant could even collude with the original patent-holder to prolong their litigation, and thereby keep the second applicant's drug off the market indefinitely.14

Yet we are not persuaded that this third anomaly suffices to show that a literal reading of the statute leads to results manifestly inconsistent with the intent of Congress. The legislative history of section 355(j)(5)(B)(iv) is limited, and fails utterly to specify or even provide any signals as to whether Congress intended that a second ANDA applicant who was not sued for patent infringement would have to wait until one of the statutory triggers was satisfied, or instead be

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14 An amicus brief filed by Biovail Corporation International dramatically illustrates an analogous risk, not necessarily involving collusion. Biovail was the second applicant to file a paragraph IV ANDA for a generic version of a heart medication. Biovail was not sued by the pioneer drug company. The first applicant and the pioneer drug company are now in litigation, and, Biovail claims, the pioneer is paying the first applicant some $10 million per quarter in exchange for the first applicant's agreement not to sell its product after the 30-month waiting period expires. Under these circumstances, neither party would seem to have maximum incentive to bring the litigation to a close.

able to immediately market its product. Congress may very well never even have thought about this question. But it is not inconceivable that Congress meant what the statute says, i.e., that the second applicant would have to wait for the first lawsuit to finish. The fact that a patent-holder fails to sue an ANDA applicant does not necessarily mean that it has concluded that the applicant did a good job of designing around its patent. The patent-holder might have simply made a mistake, and negligently failed to file suit (or filed a few days after the end of the 45-day window). If a second ANDA applicant who is not sued by the patent-holder is allowed to immediately market its product, then the patent-holder's error will have unfairly deprived the first applicant of the benefits of the exclusivity period. Moreover, even if the second applicant is sued, the successful-defense requirement will allow him to receive FDA approval immediately once the 30-month waiting period expires. Given the nature of litigation, the first applicant's patent-infringement suit could easily take longer than thirty months. The successful-defense requirement may therefore have the effect of allowing many ANDA applicants to sell their products without regard to the exclusivity period, a result that Congress might not have intended.15

Additionally, there may be other ways in which a second applicant with a better product can bring that product to market before the first lawsuit terminates. Amicus curiae, Teva Pharmaceutical Inc. ("Teva"), has pointed to one possibility. Teva observes that the court-decision trigger, by its terms, can be satisfied by any "decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed." Teva claims that the actions "described in clause (iii)" are not

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15 Under the FDA's regulation, once a later applicant's drug has been approved, it will apparently remain on the market even if the exclusivity period later begins to run. The regulation only applies the 180-day exclusivity period to ANDAs that are "subsequent" to a successful defense by the first applicant, 21 C.F.R. s 314.107(c)(1), and an ANDA that has already been approved does not fall in this category.

limited to infringement suits by the patent-holder, because the last two sentences of clause (iii) say:

> Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of Title 28 for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

21 U.S.C. s 355(j)(5)(B)(iii). Thus, Teva says, a declaratory judgment action provides an alternative way of satisfying the court-decision trigger. An ANDA applicant who doesn't want to wait for the first applicant's patent infringement litigation to finish can bring its own declaratory judgment action against the patent-holder, and, if the second applicant prevails, the court-decision trigger will be satisfied, and it will be allowed to market its product.

Teva's argument is elegant and textually persuasive. It also provides a particularly appropriate solution in cases in which the second applicant has done a better job of designing around the pioneer drug manufacturer's patent than the first did: in such cases, the second applicant should find it (relatively) easy to win a declaratory judgment action against the patent-holder. Teva's reading thus rewards those applicants (and only those applicants) who have built a better mousetrap.

Teva's reading is not, however, flawless. One difficulty is that the 180-day exclusivity period will seemingly always go to the first applicant, no matter whose suit satisfies the court-decision trigger; the statute provides that any applications after the first one "shall be made effective not earlier than one hundred and eighty days after" the court-decision trigger is satisfied. 21 U.S.C. s 355(j)(5)(B)(iv).16 It seems odd to reward the first applicant if some later applicant was the

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16 This is the most natural reading of the statute, but we do not necessarily find that it is the only permissible reading.

party that actually prevailed in the patent-infringement litigation.17

Mylan has also noted what may be a more serious fly in the (patented) ointment. In order to satisfy the Constitution's case or controversy requirement, a party filing a declaratory judgment action must show that there is a controversy of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Federal Express Corp. v. Air Line Pilots Ass'n, 67 F.3d 961, 964 (D.C. Cir. 1995) (quoting Maryland Casualty Co. v. Pacific Coal & Oil Co., 312 U.S. 270 (1941)). To employ Teva's declaratory-judgment device, a party would therefore need to demonstrate a "reasonable apprehension of facing a lawsuit." Federal Express Corp., 67 F.3d at 964. The Federal Circuit has exclusive jurisdiction over appeals in actions for patent infringement. 28 U.S.C. s 1292(c). Under the Federal Circuit's caselaw, a declaratory judgment plaintiff must be able to point to some conduct by the patent-holder that suggests that the plaintiff is at risk of being sued; the fact that the patent-holder has sued others is "pertinent," but "not always conclusive." See West Interactive Corp. v. First Data Resources, 972 F.2d 1295, 1297-98 (Fed. Cir. 1992). An ANDA applicant seeking to bring a declaratory judgment action might have difficulty in meeting this test, especially if the patent-holder disclaims any intention of bringing suit.18

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17 Indeed, the first applicant may still be enmeshed in patent-infringement litigation when the 180-day period begins, and therefore be unable to take advantage of the exclusivity period.

18 One way of eliminating strategic behavior of this kind might be for the FDA to provide by regulation that a court decision ruling that an ANDA applicant cannot reasonably anticipate suit by a patent-holder is equivalent, for purposes of section 355(j)(5)(B)(iv), to a ruling that the patent is invalid or not infringed. After all, the purpose of the scheme set up by section 355(j)(5)(B) is to allow the patent-holder an opportunity to defend its patent. If the patent-holder declines even to create enough adversity to support a declaratory judgment action, it might well be fair to deem the patent-holder to have conceded noninfringement, at least for purposes of the statutory scheme. Certainly, there would be no danger

The problem of the meritorious second applicant is a real one, but the successful-defense requirement is too blunt an instrument to solve it. The requirement cannot be reconciled with the literal language of the statute, and alters the statutory scheme in a number of ways that do not clearly serve congressional intent. We do not, of course, foreclose the FDA from attempting to address the problem of the meritorious second applicant in some narrower way, as long as that solution conforms to the statute. For now, however, we are presented with the successful-defense requirement, and we uphold the district court's decision to enjoin the FDA's enforcement of that requirement.

B.Upjohn's Motion to Intervene

We now turn to Upjohn's appeal of the district court's denial of its motion to intervene. The district court denied Upjohn's motion on two grounds: first, that Upjohn's motion was mooted by the grant of the preliminary injunction, and second, that s 355(j)(5)(B)(iv) "does not provide a cognizable interest upon which a pioneer patent owner or an NDA owner can challenge the approval of an ANDA." We find that the district court was in error on both grounds.

A motion to intervene as of right turns on four factors: (1) the timeliness of the motion; (2) whether the applicant "claims an interest relating to the property or transaction which is the subject of the action," Fed. R. Civ. P. 24(a); (3) whether "the applicant is so situated that the disposition of

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in such a case that the patent-holder's failure to enforce its patent is attributable to a mistake.

Moreover, the Federal Circuit has had no occasion to decide whether there is "a controversy of sufficient immediacy and reality" to support a declaratory judgment action, Federal Express Corp., 67 F.3d at 964, when the plaintiff requires a judgment under section 355(j)(5)(B) in order to bring its product to market. It is possible that such a statutorily-created bottleneck, coupled with the statute's express reference to declaratory judgment actions as a means of relieving that bottleneck, might suffice to allow a plaintiff to show the existence of a "case or controversy" without demonstrating an immediate risk of being sued.

the action may as a practical matter impair or impede the applicant's ability to protect that interest," id.; and (4) whether "the applicant's interest is adequately represented by existing parties." Id. To the extent that a district court's ruling on a motion to intervene as of right is based on questions of law, it is reviewed de novo; to the extent that it is based on questions of fact, it is ordinarily reviewed for abuse of discretion. See Massachusetts School of Law at Andover, Inc. v. United States, 118 F.3d 776, 779-80 (D.C. Cir. 1997) (noting, however, that application of the abuse-of-discretion standard seems anomalous in some circumstances). The issues that Upjohn raises on its appeal are all pure questions of law, so we apply de novo review.

The district court erred in finding that Upjohn's motion to intervene was moot. The district court had entered only a preliminary injunction, not a permanent injunction. The district court presumably would have considered new evidence or new arguments in future proceedings, had Upjohn (or some other party) wished to present them. And intervening even after the injunction had been issued would have allowed Upjohn to participate in the appeal of the injunction. See Massachusetts School of Law at Andover, 118 F.3d at 779 (discussing intervention before the district court for purposes of appeal).

The district court was also in error in finding that Upjohn did not "claim[ ] an interest relating to the property or the transaction which is the subject of the action," as is required by Federal Rule of Civil Procedure 24(a)(2). Rule 24(a) "impliedly refers not to any interest the applicant can put forward, but only to a legally protectable one." Southern Christian Leadership Conference v. Kelley, 747 F.2d 777, 779 (D.C. Cir. 1984). Thus, a party that seeks to intervene as of right must demonstrate that it has standing to participate in the action. See id. There is no dispute that Upjohn has constitutional standing; numerous cases have found that a firm has constitutional standing to challenge a competitor's entry into its market. See, e.g., Association of Data Processing Serv. Orgs., Inc. v. Camp, 397 U.S. 150, 152 (1970) ("Data Processing ").

Mylan argues, however, that Upjohn is not within the "zone of interests" of section 355(j)(5)(B)(iv), and that it therefore lacks prudential standing. We do not agree. The first step in the prudential standing analysis is to identify the interests protected by the statute. To do so, we consider the purposes of the specific statutory provision that is at issue (here, section 355(j)(5)(B)(iv)), read in the context of the statutory scheme as a whole. See Bennett v. Spear, 117 S. Ct. 1154, 1167 (1997); Clarke v. Securities Industry Assoc., 479 U.S. 388, 401 (1987) (stating that a court is "not limited to considering the statute under which respondents sued, but may consider any provision that helps us to understand Congress's overall purposes...."). The purpose of section 355(j)(5)(B)(iv) is to provide a reward, in the form of an exclusivity period, to generic drug companies that are the first to file paragraph IV ANDAs. Section 355(j)(5)(B)(iv) is not intended to benefit pioneer drug companies directly. Indeed, quite the opposite is true: the provision is intended to reward generic drug manufacturers who challenge pioneer drug companies' patents. Thus, in the nomenclature of this circuit's caselaw, Upjohn cannot show that it is an "intended beneficiary" of section 355(j)(5)(B)(iv). Scheduled Airlines Traffic Offices, Inc. v. Dept. of Defense, 87 F.3d 1356, 1359 (D.C. Cir. 1996) ("Scheduled Airlines").

But a plaintiff can be within the zone of interests of a statute even in the absence of "an indication of congressional purpose to benefit the would-be plaintiff." Clarke, 479 U.S. at 399-400. As the Court recently made clear in National Credit Union Administration v. First National Bank & Trust Co., 118 S. Ct. 927 (1998) ("NCUA "), a plaintiff only needs to show that its interest is among those "arguably ... to be protected" by the statute. Id. at 935 (quoting Data Processing, 397 U.S. at 153) (emphasis added). This analysis focuses, not on those who Congress intended to benefit, but on those who in practice can be expected to police the interests that the statute protects. In NCUA, the provision before the Court imposed a rule called the "common bond requirement," which limits the membership of credit unions to "groups having a common bond of occupation or associa-

tion." 12 U.S.C. s 1759 (1994). The question for the Court was whether a group of banks who had an interest in limiting the markets that credit unions could serve were within the zone of interests of this provision. The Court found that the common bond requirement was intended to "reinforce the cooperative nature of credit unions, which in turn was believed to promote their safety and soundness and allow access to credit by persons otherwise unable to borrow." NCUA, 118 S. Ct. at 935 n.6. The Court reasoned that "by its very nature, a cooperative institution must serve a limited market," id., so that there is an "unmistakable" link between the statute and a "limitation on the markets that federal credit unions can serve." Id. at 935 & n.6. The Court concluded that limiting the markets served by credit unions is therefore an interest "arguably to be protected" by the statute, so that the banks had prudential standing.

The test applied by NCUA is not far removed from this circuit's "suitable challenger" test. See, e.g., Scheduled Airlines, 87 F.3d at 1359-61 (applying this test). Under the "suitable challenger" test, a plaintiff must demonstrate that its "interests are sufficiently congruent with those of the intended beneficiaries that the litigants are not 'more likely to frustrate than to further ... statutory objectives.' " Id. at 1359 (quoting First Nat'l Bank & Trust Co. v. National Credit Union Admin., 988 F.2d 1272, 1275 (D.C. Cir. 1993) (quoting Clarke, 479 U.S. at 397 n.12)). NCUA allows a plaintiff to demonstrate that its interest and the interest served by the statute have, by their "very nature," an "unmistakable" link. NCUA, 118 S. Ct. at 935 & n.6; in other words, the plaintiff may show an inevitable congruence between the two interests. The two standards are thus very similar.

It seems clear under NCUA that Upjohn has prudential standing. Here, Upjohn is seeking to enforce (its interpretation of) section 355(j)(5)(B)(iv), a statute by which Congress sought to regulate the timing of generic drug manufacturers' entry into the market. Although the statute speaks directly only to freeing the first generic drug company to file a

paragraph IV ANDA from competition from other generic drug manufacturers, this necessarily entails freeing the pioneer drug producer from such competition as well. Thus, Upjohn's interest in limiting competition for its product is, "by its very nature," NCUA, 118 S. Ct. at 935 n.6, linked with the statute's goal of limiting competition between generic manufacturers. See also MD Pharmaceutical, Inc. v. Drug Enforcement Admin., 133 F.3d 8, 12-13 (D.C. Cir. 1998) (finding that a drug company was within the zone of interests of an "entry-restricting" statute that regulated entry into its market); Scheduled Aircraft, 87 F.3d at 1360-61 (finding that a party seeking to enforce a "statutory demarcation" is a suitable challenger) (quoting First Nat'l Bank & Trust, 988 F.2d at 1278).

Upjohn need not show anything more than that it has standing to sue in order to demonstrate the existence of a legally protected interest for purposes of Rule 24(a). See Mausolf v. Babbitt, 85 F.3d 1295, 1299-1302 (8th Cir. 1996) (finding that a showing of standing suffices to demonstrate a legally protected interest for purposes of Rule 24(a)); but cf. United States v. 39.96 Acres of Land, 754 F.2d 855, 859 (7th Cir. 1985) (finding, on the peculiar facts of that case, that more than a showing of standing was required). We therefore reject the district court's contrary conclusion that Upjohn did not have a sufficient interest in the action to intervene.

The district court never reached the remaining elements of the Rule 24(a) analysis--timeliness, the risk that Upjohn's interests would be impaired, and whether Upjohn's interests were already adequately represented in the litigation. Upjohn has included in its brief on this appeal a number of arguments for the affirmance of the district court's injunction. In order to determine whether Upjohn is properly a party to the appeal of the injunction question, we must reach the remaining Rule 24(a) issues. See Dimond v. District of Columbia, 792 F.2d 179, 193 (D.C. Cir. 1986) (similarly addressing Rule 24(a) issues that the district court had, after making an erroneous legal ruling, failed to reach); see also

Mausolf v. Babbitt, 125 F.3d 661, 666-67 (8th Cir. 1997) (holding that if the court of appeals reverses the district court's denial of a party's motion to intervene, that party may participate in an appeal of a later ruling in the same litigation, if it has met the procedural requirements for doing so). As to timeliness, Upjohn sought to intervene a few weeks after Mova initiated its action, and before the district court ruled on the preliminary injunction; this cannot be regarded as untimely. Upjohn's interests were also at risk; Upjohn was in danger of losing market share to Mylan if the district court denied the injunction and allowed Mylan's product on the market. Finally, as to adequacy of representation, Mova is a generic drug manufacturer, and therefore might have strategic reasons not to press certain arguments available to Upjohn in anticipation of (perhaps) finding itself in Mylan's situation in a future case. We thus conclude that Upjohn was entitled to intervene as of right, and that Upjohn is therefore a proper party to the appeal of the injunction order and in all further proceedings in the district court.19

III. Conclusion

We find that the FDA exceeded its statutory authority in imposing the successful-defense requirement as a prerequisite to the invocation of the 180-day exclusivity rule by a first applicant under section 355(j)(5)(B)(iv). The successful-defense requirement is inconsistent with the statutory text and structure, and is not justified by a need to protect the essential function of the statute or a clear congressional intent. We therefore affirm the district court's decision to strike down the successful-defense requirement.

As to Upjohn's motion to intervene, we conclude that the district court erred in finding that Upjohn's motion was moot and that Upjohn did not have a sufficient interest in the

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19 Upjohn also challenges the district court's denial of its motion for permissive intervention under Federal Rule of Civil Procedure 24(b). Because we find that Upjohn was entitled to intervene as of right, we do not reach this issue.

subject-matter of the litigation. We also find that the other elements of Rule 24(a) have been met by Upjohn, and reverse the district court's denial of Upjohn's motion. Upjohn is properly a party to this appeal, and to any proceedings on remand.

So ordered.